SUSPICIOUS ORDER REPORTING POLICY AND PROCEDURE

It is the policy of Bergen Brunswig Drug Company to comply with all Federal, State, and Local laws pertaining to the storage, handling, and reporting of controlled substances. The division manager is responsible for insuring that his/her division is in compliance with the following procedures pertaining to suspicious orders of controlled substances.

I. A. What is a suspicious order?

DEA regulation, 21 CFR 1301.74(b), defines a suspicious order as follows: "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

B. What is the division manager's responsibility concerning suspicious orders?

DEA regulation, 21 CFR 1301.74(b) states: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the district office of the administration in his area of suspicious orders when discovered by the registrant."

Starting with those very broad definitions of the DEA regulations contained in the Code of Federal Regulations (CFR) provided to each division, Bergen Brunswig Drug Company, in conjunction with DEA Headquarters in Washington, D.C., developed the following procedures that meet the federal reporting requirements. The division manager must insure that all division personnel involved in the handling or reporting of controlled substances are instructed in, and thoroughly familiar with the procedures for handling suspicious orders, so that their division is always in compliance with DEA regulations and company policy, as it pertains to suspicious order reporting. Because these procedures have been accepted by DEA, compliance with them is mandatory at all Bergen Brunswig Drug Company divisions.

II. Reports

The following computer reports for each division are produced monthly by the Orange Data Center and are picked up by the RCSS Department upon notification by the Data Center that the reports are ready. The reports are produced in one hard copy and one electronic copy that is put into express mail to all divisions. The RCSS Department has taken the responsibility for sending the respective hard copy computer reports to DEA for all drug divisions by sending the report to the appropriate DEA office, Certified Mail Return Receipt Requested.

Report A07-455-01M (Example 1)
Divisional Recap, Variance Report, ARCOS Items By Pharmacy.

The purpose of this report is to list total customer purchases for the current month that exceed predetermined multiples of the average monthly purchases of the division customers broken down into certain families of drugs. The program reads the current sales history file to calculate averages to be used as reporting criteria. The program produces a report for pharmacies and a separate report for hospitals by ARCOS and other scheduled items. The monthly average times factor for ARCOS items is presently set by DEA at 3 times the monthly average.

Report A07-455-03M (Example 2)
Customer Recap, Variance Report, ARCOS Items By Pharmacy.

This report lists all the customers alphabetically, within each DEA base code limit and lists the actual quantity purchased. This recap gives an overview, by DEA base code, of all customers who purchased quantities in excess of the ingredient limit.

Report A07-455-04M (Example 3)
Divisional Recap, Variance Report, Other Items By Pharmacy.

This report is exactly the same report as A07-455-01M (ARCOS Items). The only difference is that it covers scheduled drugs other than ARCOS items and the monthly variance factor is presently set by DEA at 8 times the monthly average.

Report A07-455-05M (Example 4)
Customers Exceeding Division Averages, Variance Report, Other Items By Pharmacy.

This report is exactly the same as A07-455-02M except that it covers all scheduled items other than ARCOS items. Emphasis should be placed on reviewing this report in the same manner as A07-455-02M, and for the same reasons.

Report A07-455-06M (Example 5)
Customer Recap, Variance Report, Other Items By Pharmacy.

This report is the same as A07-455-03M except that it uses 8 times the monthly average to determine the ingredient limit and includes all scheduled drugs other than ARCOS items.

Report A07-455-07M (Example 6)
Divisional Recap, Variance Report, ARCOS Items By Hospital.

Report A07-455-08M (Example 7)
Customers Exceeding Division Averages Variance Report, ARCOS Items By Hospital.

Report A07-455-09M (Example 8)
Customer Recap, Variance Report, ARCOS Items By Hospital.

Report A07-455-10M (Example 9)
Divisional Recap, Variance Report, Other Items By Hospital.

Report A07-455-11M (Example 10)
Customers Exceeding Division Averages, Variance Report, Other Items By Hospital.

Report A07-455-12M (Example 11)
Customer Recap, Variance Report, Other Items By Hospital.

It is imperative that each division manager understand that these computer reports do not relieve them of their responsibility to report suspicious orders, especially large single orders. Remember, the reports contain information on actual sales only and do not necessarily reflect actual orders. All the above reports are in the same format and contain the same information as the ARCOS Reports. They were broken out for you to make them easier to read and easier to zero in on customers who consistently exceed the DEA base code ingredient limit. These are the customers that you and your division must scrutinize closely. If these customers' orders fit the suspicious order criteria explained above, you must contact DEA to report the order before actually shipping the merchandise. This must be done even if you decide to cut the order back for business reasons. Again in this case, it is the order that is suspicious, not the actual shipment. Remember, all contact with the DEA must be recorded on a DEA Contact Form (Form 72).